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Proposed Registration Decision PRD2016-31

Garlic Juice

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Overview

Proposed Registration Decision for Garlic Juice

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of U C Garlic Juice and Mosquito Barrier Commercial, containing the technical grade active ingredient garlic juice, to repel mosquitoes in yards, park grounds and grassy areas.

U C Garlic Juice Technical (Registration Number 31021) and Mosquito Barrier (Registration Number 31022) are fully registered in Canada to repel mosquitoes in residential outdoor environments. The detailed review for garlic juice can be found in Proposed Regulatory Decision PRD2013-18, *Garlic Juice* and Registration Decision RD2014-09, *Garlic Juice*. The commercial applications represent a new use of the active ingredient garlic juice.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of U C Garlic Juice and Mosquito Barrier Commercial.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on U C Garlic Juice and Mosquito Barrier Commercial, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on U C Garlic Juice and Mosquito Barrier Commercial, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Garlic Juice?

Garlic juice is an extract of garlic (*Allium sativum* var. *sativum*) that can be used to repel mosquitoes from outdoor locations such as commercial properties, gardens, golf courses, parks, recreational areas and residential properties. It is the active ingredient in the product Mosquito Barrier Commercial.

Health Considerations

Can Approved Uses of Mosquito Barrier Commercial Affect Human Health?

Garlic juice is unlikely to affect your health when used according to label directions.

Exposure to garlic juice may occur when handling and applying the product, Mosquito Barrier Commercial, as well as during activities following application. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, garlic juice, is of low acute toxicity by the oral and dermal routes, may be a skin and eye irritant, and a possible dermal sensitizer. Because garlic is a known mucosal irritant, inhalation of garlic juice mist or vapour may result in throat and respiratory tract irritation. The end-use product, Mosquito Barrier Commercial, is of low acute toxicity by both the oral and dermal route, may be a skin and eye irritant, and a possible dermal sensitizer. Cautionary statements alerting the user to the potential as a skin and eye irritant and dermal sensitizer are present on the product label of Mosquito Barrier Commercial.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

The data requirements for short-term toxicity, prenatal developmental toxicity, and genotoxicity were not required by the PMRA based on the long history of safe consumption of garlic as a whole foodstuff and garlic juice in natural health products.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The use of Mosquito Barrier Commercial is for non-food situations. Garlic readily degrades in the environment, so any inadvertent exposure of garlic juice to food, feed, or water from drift or direct contact is not expected to result in any dietary risk.

Occupational Risks From Handling Mosquito Barrier Commercial

Occupational risks are not of health concern when Mosquito Barrier Commercial is used according to the proposed label directions, which include protective measures.

Pesticide applicators mixing, loading and applying Mosquito Barrier Commercial to areas that attract mosquitoes such as plants, shrubs, turf, as well as under decks and porches, can come in direct contact with garlic juice on the skin or through inhalation. Following the precautionary label statements aimed at minimizing exposure to the product will ensure that users are appropriately protected. The label will also specify that anyone mixing, loading or applying Mosquito Barrier Commercial must wear a long-sleeved shirt, long pants, waterproof gloves, shoes plus socks and protective eyewear.

Bystander exposure from spray drift is expected to be negligible if the precautionary label statements are observed by the applicator.

Postapplication exposure is possible for individuals who immediately enter freshly treated areas. Following application of Mosquito Barrier Commercial to outdoor areas where mosquitoes are found, the transfer of garlic juice to an individual who is not sensitive to garlic will not pose a health concern.

As some individuals may be sensitive or allergic to garlic, precautionary statements specifying that individuals who are sensitive or allergic to garlic should avoid handling Mosquito Barrier Commercial, as well entering recently treated areas, are also present on the product label of Mosquito Barrier Commercial.

Value Considerations

What Is the Value of Mosquito Barrier Commercial?

Mosquito Barrier Commercial repels mosquitoes from outdoor areas occupied by people to reduce the annoyance caused by this pest.

Mosquito Barrier Commercial is a non-conventional product that is sprayed onto plants to repel mosquitoes, reducing their nuisance to people in the treated area. It is applied in outdoor

locations such as commercial properties, gardens, golf courses, parks, recreational areas, and residential properties. There are few alternative repellents for this use. Mosquito Barrier Commercial provides an alternative to conventional insecticides in locations where their use may be undesirable.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Mosquito Barrier Commercial to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The statement "Applicators and handlers must wear a long-sleeved shirt, long pants, waterproof gloves, shoes plus socks and protective eyewear" must be included on the product label of Mosquito Barrier Commercial for commercial applicators.

Next Steps

Before making a final registration decision on U C Garlic Juice and Mosquito Barrier Commercial, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on U C Garlic Juice and Mosquito Barrier Commercial (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Garlic Juice

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Please refer to PRD2013-18, *Garlic Juice*.

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product – U C Garlic Juice

Please refer to PRD2013-18, *Garlic Juice*.

End-Use Product–Mosquito Barrier Commercial

Property	Result
Colour	Yellowish sand
Odour	Strong garlic odour
Physical state	Liquid
Formulation type	Liquid
Guarantee	99.3%
Container material and description	Plastic jugs or plastic drums (3.79 L – 208 L)
Density	1.03-1.1 g/mL
pH	3.43
Oxidizing or reducing action	Not required
Storage stability	Product is stable at 20°C for 36 months minimum.
Corrosion characteristics	Non-corrosive to the packaging material.
Explodability	Product is not potentially explosive.

1.3 Directions for Use

Mosquito Barrier Commercial is a commercial class repellent for use in outdoor locations including commercial properties, gardens, golf courses, parks, recreational areas, residential properties and under decks and porches and to repel mosquitoes. It is applied as a broadcast spray to plants that are not used as food for people or feed for animals. It may be re-applied after heavy rain or if mosquitoes continue to be a problem.

Mosquito Barrier Commercial is applied in water at the rate of 30-60 mL of product/L of water. To aid mixing and spreading of the spray solution, up to 10 mL of mild liquid soap (do not use detergent) per litre of water may be added. If a sticker is desired to aid retention of the product on plants, up to 20 mL of vegetable oil such as canola or corn oil (excluding soybean or peanut oil) with up to 10 mL of mild liquid soap per litre of water may be added.

1.4 Mode of Action

The mode of action for garlic juice is described in the PRD2013-18, *Garlic Juice*.

2.0 Methods of Analysis

Not required for garlic juice.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of data available in the literature on the toxicology of garlic juice was conducted by the PMRA. Please refer to PRD2013-18, *Garlic Juice*.

3.2 Food Residue Exposure Assessment

A food residue exposure assessment was not required for the non-food/feed uses of Mosquito Barrier Commercial.

3.3 Occupational and Residential Exposure Assessment

Garlic Juice is registered for domestic use to repel mosquitoes in residential outdoor environments. For residential exposure assessments, please refer to PRD2013-18, *Garlic Juice*. Occupational exposure assessments for workers were considered for the new commercial use.

Mosquito Barrier Commercial is a concentrated garlic solution (99.3% w/w garlic juice) to be diluted by mixing 30 mL per litre of water or 60 mL per litre of water if mosquitoes are already present. In addition, options for adding 10 mL of a mixing and spreading aid (water softener) in the form of liquid soap and up to 20 mL of vegetable oil as a plant retention aid are also provided on the label. Mosquito Barrier Commercial is proposed for spray application to run-off in areas that attract mosquitoes such as plants, shrubs, turf, as well as under decks and porches, in a commercial setting. It is expected that the applicator will handle 30 to 60 mL per 1 L of water per treatment.

Based on previous reviews, Mosquito Barrier Commercial is expected to be of low acute toxicity by both the oral and dermal routes. It is expected that Mosquito Barrier Commercial may be a skin and eye irritant, as well as a possible dermal sensitizer. Garlic juice, a mucosal irritant, will result in irritation when inhaled.

Due to the low toxicity of Mosquito Barrier Commercial, the long history of safe use of garlic as a food, the precautionary statements present on the label and the recommended personal protective equipment (PPE) for workers, quantitative risk assessments for mixers, loaders, applicators and bystanders are not warranted.

3.3.1 Mixer/Loader/Applicator Exposure and Risk Assessment

Mosquito Barrier Commercial use may result in exposure to the mixers, loaders and applicators, but significant risks from such exposures are not anticipated due to the low toxicity of garlic juice and adequate exposure mitigation measures recommended on the label.

Inhalation, dermal and ocular exposures are possible when handling the product. Occupational exposure to Mosquito Barrier Commercial will be minimal if workers follow label recommendations. The label has exposure reduction statements to protect workers against any unnecessary risk from exposure. When handling, loading/mixing, and/or applying Mosquito Barrier Commercial, the PMRA recommends that applicators and handlers wear a long-sleeved shirt and pants, water-proof gloves, shoes plus socks and protective eyewear. The label includes precautionary statements to avoid getting on skin and in eyes, to avoid inhaling/breathing mists or vapours, and not to swallow. As some individuals may be sensitive or allergic to garlic, the precautionary statement "Individuals who are sensitive or allergic to garlic should avoid handling Mosquito Barrier Commercial" is present on the Mosquito Barrier Commercial label.

3.3.2 Postapplication Worker Exposure and Risk

There are no postapplication worker activities associated with Mosquito Barrier Commercial. The following precautionary statement is present on the label: "Individuals who are sensitive or allergic to garlic should avoid treated areas until dry or after a heavy rain."

4.0 Value

The value of Mosquito Barrier Commercial was supported based on the value information provided for the domestic class product, Mosquito Barrier. Please refer to PRD2013-18, *Garlic Juice* for further information.

There are few commercial class area repellents to reduce annoyance from mosquitoes. Another garlic-based active ingredient, garlic oil, is registered to repel mosquitoes from outdoor areas, and permethrin can be applied to the perimeter of an area to reduce annoyance caused by mosquitoes. Mosquito Barrier Commercial provides an alternative to conventional insecticides in locations where their use may be undesirable. It can be used in conjunction with other pest control practices such as eliminating mosquito breeding sites. People may also use a personal insect repellent to reduce the chances of being bitten by mosquitoes.

5.0 Summary

5.1 Human Health and Safety

The available toxicological information on garlic is adequate to identify the majority of toxic effects that may result from exposure to the active ingredient. Please refer to PRD2013-18, *Garlic Juice*.

Mixers, loaders and applicators handling Mosquito Barrier Commercial and workers re-entering treated areas are not expected to be exposed to levels of garlic juice that will result in health risks of concern when Mosquito Barrier Commercial is used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

Exposure to individuals entering treated areas is not expected to result in health risks of concern when Mosquito Barrier Commercial is used according to label directions.

5.2 Value

Mosquito Barrier Commercial is a non-conventional product that is applied to outdoor areas in order to reduce annoyance from mosquitoes. There are few alternative repellents for this use. It provides an alternative to conventional insecticides in locations where their use may be undesirable.

6.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of U C Garlic Juice and Mosquito Barrier Commercial, containing the technical grade active ingredient garlic juice, to repel mosquitoes in yards, park grounds and grassy areas.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

L	litre(s)
mL	millilitre(s)
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRD	Proposed Registration Decision
TGAI	technical grade active ingredient
w/w	weight per weight

Appendix I Tables and Figures

Table 1 Toxicology Endpoints for Use in Health Risk Assessment for Mosquito Barrier Commercial

Please refer to PRD2013-18, *Garlic Juice*.

Table 2 Use (label) Claims Proposed by Applicant and Accepted

Proposed label claim	Supported use claim
Pest Claim: Repels mosquitoes Location: In areas where mosquitoes are a problem such as on plants, shrubs, turf, under decks and porches in yards, park grounds & grassy areas. Concentration: 30-60 mL product/L of water Rate: Spray until run off. Reapplication interval: Re-apply after heavy rain or if mosquitoes continue to be a problem Other: • Up to 10 mL of mild liquid soap/1 L of water may be added to aid in mixing and spreading of spray solution. • Up to 20 mL of vegetable oil (canola or corn oil; do not use soybean or peanut oil) with up to 10 mL of mild liquid soap/1 L of water may be added to aid as a sticker.	Pest Claim: As proposed. Location: On plants, shrubs, turf, under decks and porches in outdoor areas including around parks, yards, golf courses, gardens, commercial properties and recreational areas. Concentration: As proposed. Rate: As proposed. Reapplication interval: As proposed. Other: As proposed.

References

A. List of Studies/Information Submitted by Registrant

1.0 Human and Animal Health

PMRA Document Number	Reference
2517235	2015, Use Description Scenario, DACO: 5.2

2.0 Value

PMRA Document Number	Reference
2275301	2012, Benefit Information and Use History, DACO: 10.2.3.3(C)
2275302	2012, Benefit Information and Use History, DACO: 10.2.3.3(C)
2275303	2012, Benefit Information and Use History, DACO: 10.2.3.3(C)
2275305	2012, Benefit Information and Use History, DACO: 10.2.3.3(C)
2275307	2013, Benefit Information and Use History, DACO: 10.2.3.3(C)
2275309	2007, Certificate of Analysis, DACO: 10.2.1
2275310	2009, Analyses of Essential and Edible Oils, And Constituents Therein, As Candidate Repellents for the Yellow Fever Mosquito *Aedes Aegypti* L. (Diptera: Culicidae), DACO: 10.2.1
2275312	2012, Benefit Information and Use History, DACO: 10.2.3.3(C)
2275315	2013, Scientific Rationale Summary, DACO: 10.2.3.1